



WEEK ENDING MAY 23, 2014

OPP Weekly Activity Report

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PESTICIDE RE-EVALUATION DIVISION

OPP Publishes Voluntary Cancellation Notice. On May 20, 2014, a notice was published in the *Federal Register* to announce EPA's receipt of requests for the cancellation of 63 pesticide product registrations, which included 16 pyrethroid insecticides. All registration cancellations were voluntarily requested by the registrants. The EPA is providing a 30-day public comment period on the proposed requests. (John Pates, 703-308-8195)

Denatonium Saccharide Proposed Interim Decision for Registration Review Signed.

On May 20, 2014, the Proposed Interim Decision for denatonium saccharide was signed and is scheduled to open for a 60-day public comment period beginning on June 4, 2014. Denatonium Saccharide is a bittering agent in squirrel, vole, dog and cat repellent used on outdoor surfaces and structures such as trees, fences, poles, decks, planters, siding, garbage cans, furniture, seeds, and bulbs. The EPA conducted a qualitative human health risk assessment and did not identify any risks of concern. The environmental fate and ecological risk assessment identified potential risks for birds and mammals. A no-effect determination was reached for all species except for those that may be affected from the consumption of seeds or bulbs and terrestrial insects. For all other listed species, the EPA made a may affect but not likely to adversely affect determination.

No label changes or other mitigation measures have been proposed in the interim decision. A final decision on the denatonium saccharide registration review case will occur after the Federal Food, Drug and Cosmetic Act Section 408(p) Endocrine Disruptor Screening Program determination has been made and after receiving concurrence from the U.S. Fish and Wildlife Services on the NLAA endangered species determinations. If there are no significant comments or additional information submitted to the docket during the comment period to change this proposed decision, the EPA plans to issue an Interim Registration Review Decision. (Cathryn Britton, 703-308-0136)

OPP Meets with Bayer CropScience and Tessenderlo Kerley, Inc. to Discuss Carbaryl and the Design of a Bee Tunnel Study.

On May 20, 2014, representatives from Bayer CropScience, Tessenderlo Kerley, Inc., PRD and EFED met to discuss the design of a bee tunnel study. Carbaryl is an N-methyl carbamate insecticide registered for use in a wide variety of agricultural and residential settings. The tunnel study is a requirement of the carbaryl registration review data call in. The registration review docket for carbaryl (EPA-HQ-OPP-2010-0230) opened in September 2010. (Eric Miederhoff, 703-347-8028)

2,4-DP-p Final Work Plan for Registration Review Signed. On May 20, 2014, PRD completed the Final Work Plan (FWP) for 2,4-DP-p, a non-systemic, non-agricultural herbicide in the phenoxy family. 2,4-DP-p is registered to control a

variety of noxious weeds and brushes on commercial and residential lawns/outdoor areas; golf courses; sod farms; forest trees; and uncultivated areas such as rights-of-way, roadsides, and airports. During the 60-day public comment period on the registration review Preliminary Work Plan, which closed on February 18, 2014, the agency received five public comments. Comments were received on the planned ecological and human health risk assessments, data requirements, and water quality concerns. The comments did not result in changes to the planned risk assessments or data requirements. The FWP will post shortly in the 2,4-DP-p public docket (EPA-HQ-OPP-2013-0726). (Kaitlin Keller, 703-308-8172)

Imazapic Registration Review Focus Meeting Held. On May 20, 2014 the OPP registration review team (from BEAD, EFED, HED, RD and PRD) held a focus meeting with the technical registrants (BASF and MANA/ADAMA), as well as representatives from the Bureau of Land Management (BLM), the USDA's Forestry Service (FS) and the Office of Pesticide Pest Management Policy (OPMP). At this meeting the registration review team and stakeholders discussed the registration review process, shared information on uses and benefits, and tried to identify any potential issues that could impact the registration review of imazapic. The BLM and the Forestry Service identified previous assessments and consultations that could be useful to the endangered species assessment along with data on usage on federally-managed lands. The registrants also provided valuable information on the specific uses and benefits of imazapic products and OPMP shared information on resources that may be helpful during the registration review process. Imazapic is an imidazolinone herbicide registered for use on peanuts, pasture/rangeland and non-agricultural/non-crop areas. The docket for Imazapic is scheduled to open in September 2014. (Ricardo Jones, 703-347-0493)

ANTIMICROBIALS DIVISION

Stakeholder Collaboration on Gaining Regulatory Acceptance of Skin and Eye *in vitro* Methods for Use in Evaluating Pesticides. On Tuesday May 20, 2014 Crop Life America (CLA) hosted a discussion with OPP, NIH, PMRA, PETA, PCRM, Crop Life Canada, and member companies (BASF, Dow, DuPont) with the objective of creating a path forward for regulatory acceptance of *in vitro* test methods for classifying and labeling of pesticides for acute skin and eye irritation, and skin sensitization, potential. Anna Lowit (HED) Co-Chair ICCVAM helped organize this effort in coordination with the 21st C Toxicology PPDC Workgroup, Chair Jennifer McLain (AD). HED, AD, and RD are collaborating on this activity. At the meeting, individual companies presented information on their in-house *in vitro* testing programs and shared their perspectives on the benefits of and barriers to adopting *in vitro* alternatives for acute toxicology testing. OPP encouraged data sharing and analysis to enable acceptance of these alternative tests for regulatory decisions. At the conclusion of the meeting, all parties agreed that we

share a common goal. CLA will bring a proposal to their members that would enable gathering data in a blinded fashion. OPP is working with OGC to develop guidance to industry regarding incident reporting requirements and labeling questions. (Jennifer McLain, 703-308-0293)

AD Presents Alternative Eye Assay Policy for Antimicrobial Products with Cleaning Claims to Crop Life America: Dr. Timothy McMahon, met with Crop Life America representatives on Wednesday, May 21, 2014, to present the Antimicrobials Division's (AD) policy on an alternate testing framework for determining eye irritation. The purpose of this meeting was to present the development of the policy within AD and the process used to engage registrants to submit studies using the three *in vitro/ex vivo* tests discussed in the policy (Bovine Corneal Opacity and Permeability Assay, Epiocular Assay, and Cytosensor Assay). As part of expanding the scope of the policy, Crop Life America was encouraged to submit data using these tests on conventional pesticides, as it would provide the basis for determining whether the approach discussed in the current eye policy can support classification and labeling for eye irritation of conventional pesticides. (Tim McMahon, 308-6342).

ACC Meeting on New Proposal for the AMTTC Project – AD Staff met with representatives from the American Chemistry Council on Thursday, May 22, 2014 to discuss a proposal for a second Antimicrobial Threshold of Toxicological Concern (AMTTC) project. The new proposal builds on the foundation of the project conducted by the International Life Sciences Institute (ILSI). ACC proposes to use chemoinformatics to develop a distribution of potency for compounds rather than relying on the Cramer classes and will develop a new decision tree based on chemotype and toxicity. ACC will follow up by sending a more detailed proposal in the next few weeks which AD will evaluate in coordination with HED, RD, OPPT, and ORD. (Steven Weiss/AD 703.308.8293)

REGISTRATION DIVISION

Section 18 Authorized for Use of Terbufos on Cotton in Georgia On May 20, 2014, EPA authorized a Section 18 Emergency Exemption to the Georgia Department of Agriculture for the use of terbufos formulated as Counter 20G Systemic Insecticide/Nematicide (EPA Registration 5481-562) on cotton to control southern root knot nematodes. The loss of a standard tool, aldicarb, to manage nematodes has resulted in a non-routine and urgent situation for cotton growers in Georgia. Approximately 300,000 acres of cotton in limited cotton-producing counties are expected to be treated. This Section 18 authorization expires July 1, 2014. (Stacey Groce, 703-305-2505; Tawanda Maignan, 703-308-8050)

Notice of Receipt Published for Multiple Section 18 Requests On May 21, 2014, the *Federal Register* published a combined notice announcing the receipt of

three applications for emergency exemptions under Section 18. Two were from the Florida Department of Agriculture and Consumer Services (FDACS) for the following uses: clothianidin on up to 125,376 acres of young citrus trees to control the transmission of Huanglongbing disease caused by Asian Citrus Psyllid; and streptomycin to control citrus canker (*Xanthomonas citri*) on up to 54,000 acres of grapefruit grown for fresh market. One application was from the Georgia Department of Agriculture (GDA) for the use of terbufos to control southern root knot nematodes on approximately 300,000 acres of cotton. The FDACS proposes the use of clothianidin, which belongs to the neonicotinoid class of pesticides and streptomycin, which is used in humans and animals as an antibiotic drug. The GDA proposes the use of terbufos, which belongs to the organophosphate class of pesticides. The comment period for these notices ends on May 28, 2014. (Stacey Groce, 703/305-2505; Andrea Conrath, 703/308-9356)

| Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions | | | | | |
|--|---|-----------------------------------|--------------------|-----------------------------|--------------------|
| State/Federal Agency | Chemical Emergency Exemption Number | Product Name EPA Reg/ File Symbol | Crop/Site | Pest | Authorization Date |
| Specific Exemption(s): | | | | | |
| Florida | Potassium Salt of Hop Beta Acids 14-FL-05 | HopGuard II® (Unregistered) | Beehives | Varroa Mites | 5-16-2014 |
| Nebraska | Potassium Salt of Hop Beta Acids 14-NE-01 | HopGuard II® (Unregistered) | Beehives | Varroa Mites | 5-16-2014 |
| South Dakota | Potassium Salt of Hop Beta Acids 14-SD-01 | HopGuard II® (Unregistered) | Beehives | Varroa Mites | 5-16-2014 |
| | | | | | |
| Georgia | Terbufos 14-GA-03 | Counter 20G (5481-562) | Cotton | Southern Root Knot Nematode | 5-20-2014 |
| Stacey Groce, 703/305-2505 | | | | | |
| Mississippi | Fipronil 14-MS-01 | Termidor® SC (7969-210) | Outside Structures | Tawny Crazy Ant | 5-22-2014 |
| Andrea Conrath, 703/308-9356 | | | | | |

| Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA) | | | | | |
|--|-------------------------------|---------------------|--------------|-----------|---------------|
| Chemical | Company | Registration Number | Action Code* | Due Date | Response Date |
| The Fungicide Branch granted: | | | | | |
| Azoxystrobin | Syngenta Crop Protection, LLC | 100-1537 | R300 | 5/19/2014 | 5/19/2014 |
| Erin Malone, 703/347-0253 | | | | | |
| Tebuconazole | Tide International, USA, Inc. | 84229-34 | R301 | 6/3/2014 | 5/19/2014 |
| Hope Johnson, 703/305-5410 | | | | | |
| Ethephon | Direct AG Source, LLC | 83222-33 | R340 | 6/2/2014 | 5/22/2014 |
| Lindsay Roe, 703/347-0506 | | | | | |

| The Herbicide Branch granted: | | | | | |
|---|---|------------------------------------|------|----------------------|-----------|
| Sulfentrazone | Dow AgroSciences LLC | 62719-680 | R300 | 7/7/2014 | 5/16/2014 |
| Emily Schmid, 703/347-0189 | | | | | |
| Dicamba dimethylamine salt | Arysta LifeScience North America, LLC | 66330-421 | R300 | 11/1/2013 | 5/21/2014 |
| Nitrapyrin | Dow AgroSciences LLC | 62719-20 62719-583 62719-657 | R350 | 5/9/2014 5/6/2014 | 5/22/2014 |
| Dianne Morgan, 703/305-6217 | | | | | |
| Quinclorac | FMC Corporation Agricultural Products Group | 279-3463 | R310 | 6/13/2014 | 5/22/2014 |
| Mindy Ondish, 703/605-0723 | | | | | |
| Glufosinate | Albaugh, LLC | 42750-259 | R334 | 6/16/2014 | 5/22/2014 |
| 2,4-D | Winfield Solutions, LLC | 1381-247 | R350 | 6/12/2014 | 5/22/2014 |
| Grant Rowland, 703/337-0254 | | | | | |
| PRIA Categories | | | | | |
| R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix ^{(2) (3)} ; R301 – New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner ^{(2) (3)} ; R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging ^{(2) (3)} ; R334 – New product; MUP or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc.; selective data citation ^{(2) (3)} ; R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) ^{(2) (3)} ; and R350 – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) ^{(2) (3)} . | | | | | |

FIELD & EXTERNAL AFFAIRS DIVISION

FEAD Presents to the Ag Retailers Association on the Proposed WPS Changes.

The Agricultural Retailers Association hosted a webinar on May 15 for the members of its organization to highlight the proposed changes to the Worker Protection Standard. Presenter Richard Pont discussed the WPS background, reasons for the rule change, the nature of the proposed changes, the difference in the proposals compared to the current rule, the costs and benefits of the proposals, and how to submit comments to the docket. There was also a brief session for questions from the audience, and most questions focused on the proposed training requirements, the extension of the comment period, and the expected timeframe for issuance of the final rule. (Richard Pont, 305-6448)

FEAD Presents to Florida Farmworker Advocates on the Proposed WPS Changes.

The Florida Department of Agriculture and Consumer Services hosted a meeting in Apopka, Florida, on May 16 for Florida farmworker advocacy groups, FDACS

staff, and Florida extension agents to highlight the proposed changes to the WPS. About 40 WPS stakeholders, representing several Florida farmworker advocacy groups, attended the meeting either in person or through remote access. Richard Pont presented information on the WPS proposals and discussed the reasons for the rule change, the proposed changes, the costs and benefits of the proposals, and how to comment effectively in the docket. There was robust questioning from the audience on the full range of the proposals, though the majority of questions focused on the training- and hazard communication-related requirements. (Richard Pont, 305-6448)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

| OPP FOIA Request Status Report – May 12- 16, 2014 | | | | | | | |
|---|------------------|-----------------|------|------------------|---------------|-------------|-------|
| Requests Received | | Requests Closed | | | Requests Open | | |
| FY14 | <i>This week</i> | FY14 | FYTD | <i>This Week</i> | FY14 | Prior Years | Total |
| 346 | 4 | 210 | 285 | 11 | 136 | 234 | 370 |

(Ana Espinoza, 703-347-0102)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

School IPM Highlighted at National Conference on Urban Entomology (NCUE). EPA's Center of Expertise (CoE) for School IPM was invited to present at this year's NCUE held in San Antonio Texas from May 18 – 21. More than 250 attendees representing academia, government, industry and NGOs, who participated in diverse sessions ranging from 'Making School IPM Sustainable' to 'Insect Behavioral Adaptations Pose New Challenges.' During the SIPM symposia, the CoE's Sherry Glick gave a presentation titled Implementing School IPM Programs by Empowering EPA Stakeholders and Partners: Building a Smart, Sensible and Sustainable approach to pest management. The presentation focused on building national partnerships and relationships in a wholesale approach where synergism abounds. Evolving working relationships with the National Association of School Nurses, National PTA & the National School IPM Working Group were highlighted. Over 50 attendees participated in the session. Expected outcomes from the CoE attending the conference include increased collaboration and partnerships in advancing nationwide implementation of SIPM. (Sherry Glick, 214-665-6713)

ENVIRONMENTAL FATE & EFFECTS DIVISION

Aquatic Modeling Webinar Conducted with Services. EFED held an aquatic webinar with the National Marine Fisheries Service and the Fish and Wildlife Service (collectively referred to as the Services), as well as the United States Department of Agriculture, to discuss EFED's proposed aquatic modeling approach for the upcoming endangered species assessments for malathion, chlorpyrifos, and diazinon. Chuck Peck (EFED) provided an overview of EFED's Surface Water Concentration Calculator (SWCC) and how it would be used to estimate exposure concentrations in aquatic habitats pertinent to endangered and threatened species. EFED representatives answered questions on the sensitivity of the model, how parameters are selected for use in the model, and how the model would be used nationally and regionally to affect endangered species determinations. Kris Garber and Ed Odenkirchen (EFED) provided an example of a joint probability analysis process that would use the results of the SWCC, combined with a species sensitivity distribution, to inform the decision process. (Chuck Peck, 703-347-8064; Kris Garber, 703-347-8940; Ed Odenkirchen, 703-305-6449; Bill Eckel, 703-305-6451; Mark Corbin, 703-605-0033).

HEALTH EFFECTS DIVISION

National Academies Review of CA DPR Risk Assessment Process: Several EPA staff participated in the NAS/NRC review of California's Risk Assessment Process for Pesticides (Bill Jordan, Kelly Sherman, Anna Lowit, Jeff Dawson). EPA presented an overview of how OPP conducts pesticide risk assessment and how that process integrates with risk management and regulatory decision making. The panel was supplied several case studies for comparison in order to evaluate potential differences between EPA and DPR risk assessment findings and the 3 which created the most interest were iodomethane, chloropicrin, and cancer risks from dietary exposure to carbaryl. There was a substantial discussion on occupational exposure issues, fumigant risk assessment, how hazard characterization considers children, the scope of risk assessments, and how risk assessors interact with risk managers throughout the process. (Jeff Dawson, 305-7329)

HED's RAB VI Recommends a Tolerance for Malathion Public Health Use:

Malathion is an organophosphate (OP) pesticide registered on many crops for direct agricultural use. It has also been in use as mosquito adulticide / public health use for a number of years, mostly in urban areas. The registrant has been requesting the Agency for establishment of tolerances to cover residues of malathion from public health use on crops not registered for direct agricultural application. After reviewing the use pattern, formulations, monitoring data, current dietary risk estimates, and in consultation with BEAD, EFED and PRD, HED

recommended that a tolerance for the public health use be established. (Mohsen Sahafeyan, 305-0776)

Meeting with Cheminova to Discuss Inhalation Studies for Dimethoate:

Representatives from HED and PRD held a conference call with Cheminova on May 19th to discuss inhalation studies for dimethoate. Dimethoate, an organophosphate pesticide, is currently going through the Registration Review process and Cheminova is proposing to conduct several inhalation studies. HED answered questions regarding study designs and the utility of these inhalation studies for volatilization and occupational handler assessments. (Monique Perron, 347-0395; Jeffrey Dawson; Anna Lowit; Elizabeth Mendez; Elissa Reaves; Charles Smith)

Meeting with California Department of Pesticide Regulation (CDPR) to Discuss Fumigant Laboratory Tarp Testing:

Representatives from HED and PRD held a conference call with Cheminova on May 19th to discuss fumigant tarp testing at high humidity conditions vs. ambient humidity conditions. HED/PRD have developed the fumigant tarp credits using field scale flux studies conducted at high humidity conditions. The laboratory tarp testing was conducted at ambient humidity conditions and this data was used to "group" the tarps as it is not feasible to conduct field scale flux studies for all tarp types. CDPR believes the grouping should be performed using laboratory tarp testing conducted at high humidity conditions. After some discussion, it was determined that HED/PRD would continue to use laboratory tarp testing conducted at ambient humidity to group the tarps while CDPR would determine what data it would use to group the tarps at a later date. (Charles Smith, 305-0291; Jeffrey Dawson)

Meeting to Discuss Mode of Action Data for Permethrin: Representatives from the Cancer Assessment Review Committee (CARC) met on March 20th with representatives from the Permethrin Data Group II/Joint Venture (PDGII) to discuss the available mode of action (MOA) data for the synthetic pyrethroid permethrin. Permethrin is currently classified as a Category C carcinogen based on liver and lung tumors in mice. A low dose linear extrapolation approach (Q 1*) was used for quantification of human cancer risk. The proposed modes of action for the liver and lung tumors observed with permethrin were presented by the PDGII and the supportive mechanistic data were discussed. The permethrin MOA studies have already been submitted to the Agency for review; however, the MOA framework document will be submitted in the coming weeks. When all relevant information is received, the data will be presented to the CARC for review. (Karlyn Middleton, 308-0004)

CLA meeting on Global Zoning/Exchangeability: This week David Miller, Steve Funk, and James Nguyen from HED met with the CropLife America Residue Expert Working Group (CLA REWG) at the CLA office in Washington, DC. HED members

presented the results of statistical analysis using the residue database provided by PMRA to evaluate the cross-country exchangeability of field trial residues between the United States and Canada. The analysis found that there was no systematic difference in the field trial residues between the US and Canada. The results suggest that the field trial residues of same crop-pesticide in the U.S. and Canada can be pooled together to produce a larger dataset that represents the North American region. At the meeting, CLA members also discussed with HED plans to extend the US-Canada exchangeability concept to a global scale, and CLA agreed to collect additional data from already-existing field trials for use in this evaluation. To the extent to which the geographic region in which a given crop-pesticide field trial is performed does not play a significant role in determining resulting residues, field trials conducted in different countries could be combined resulting in an improved MRL at potentially lower cost. (James Nguyen, 347-0377)

NPIC Informational Meetings Held for OPP and HED: Dave Stone from Oregon State University provided OPP staff with presentations on the National Pesticide Information Center (NPIC) in order to raise awareness of how EPA and the public can utilize the program. CEB/TEB staff met with Dave Stone to discuss HED-related collaborations with NPIC including the development of a factsheet to help homeowners safely and effectively decontaminate homes where pesticide products have been overused. (Elizabeth Evans, 305-7891)

CARES Conference Call: On April 21st HED staff (David Miller, Steve Nako, David Hrdy, Bayazid Sarkar) participated in a conference call with various stakeholders related to the “next generation” update to the industry-sponsored Cumulative and Aggregate Risk Evaluation System (CARES) model. Led by the lead contractor, [Crème Global](#), the call focused on comments and revisions to the document that outlines the scope of requirements for the updated model and will be used as a basis for coding of the new software by Crème Global. (Matt Crowley, 305-7606)